IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
	:	**MDL No. 3094**
	:	**24-md-3094**
THIS DOCUMENT RELATES TO:	:	
	:	**HON. KAREN SPENCER MARSTON**
ALL ACTIONS/ALL CASES	:	

SPECIAL MASTER LAWRENCE F. STENGEL'S
REPORT AND RECOMMENDATION REGARDING PLAINTIFFS'
REQUEST FOR PRODUCTION OF ANIMAL HISTOPATHOLOGY SLIDES

This Report & Recommendation concerns a discovery dispute between the parties over the production of certain animal histopathology slides. The Plaintiffs contend the slides are relevant to their inquiry regarding FDA approval of the medications in question. Specifically, I have been assigned to address Plaintiffs' request that Defendants Eli Lilly & Company ("Lilly") and Novo Nordisk ("Novo") be required to produce animal histopathology slides (the "Slides") for 22 studies that they conducted related to the GLP-1 RA pharmaceuticals at the center of this MDL. Plaintiffs argue that the Slides are relevant to Cross Cutting Issues 2 and 3 (Preemption, General Causation and Warnings). Defendants respond that Plaintiffs have failed to show the Slides are relevant (or particularly relevant) and that the request is disproportionate to the needs of the case, especially with this phase of discovery ending on October 24, 2025. I issue this Report and Recommendation pursuant to the July 31, 2024 Order appointing me as Special Master to "oversee discovery between and among the parties and . . . resolve discovery disputes . . . ." *See* Order [ECF No. 213].

The Parties have thoroughly briefed the issues, and I have conferred with them multiple times. Having fully considered the matter, I recommend that the Court not order production of the Slides because they are only marginally relevant and because Plaintiffs' request for them is disproportionate to the needs of the case.

I. FACTUAL AND PROCEDURAL BACKGROUND

This multi-district litigation involves personal injury claims related to the Plaintiffs' use of certain GLP-1 RA's manufactured by Lilly and Novo. Plaintiffs allege that they suffered gastrointestinal injuries from these products. *See generally* Master Long Form Complaint. ("Master Compl.") [ECF No. 294]. On August 23, 2024, the Court entered a phased discovery order and permitted early discovery and motion practice on cross-cutting issues related to whether Plaintiffs' claims are preempted by federal law or fail because the warnings included in the product labeling are adequate as a matter of law. *See generally* Order [ECF No. 235]. The Parties have further agreed to early discovery and motion practice related to general causation. *See* Order, p.1, n.1 [ECF No. 282].

The Slides relate to a subset of Defendants' studies of animal testing and concern five types of tissues from three different animal species. Defs.' Aug. 11, 2025 Ltr. The Slides were a part of the underlying studies that Defendants conducted on GLP-1 RAs and may inform representations made to the FDA. *See* Pls.' Aug. 7, 2025 Ltr., pp. 1-2. As Plaintiffs explain, "[a]nimal studies provide the first evidence of adverse side effects and Defendants use animal study findings as a stepping stone to start testing in humans pursuant to FDA regulations." Pls.' July 8, 2025 Ltr. The thrust of the Slides' importance in this litigation is that the Plaintiffs would like to see what the

Defendants saw on the Slides to confirm whether it matches the content of the study reports. *See* Pls.' Aug. 7, 2025 Ltr., p. 2.

My discussions with the Parties on the Slides began in December 2024. *See* Pls.' Dec. 11, 2024 Ltr. Their discussions among themselves on this topic date back a year to September 2024. *See* Defs.' Aug. 7, 2025 Ltr. Notwithstanding the history of discussions of this issue, I was not involved in the issue for some time (between January and July), until Plaintiffs once again asked for my involvement on July 8, 2025. *See generally* Pls.' July 8, 2025 Ltr.

I have considered numerous submissions from the Parties on the Slides:

- Plaintiffs' December 11, 2024 Letter;
- Novo's December 16, 2024 Letter;
- Lilly's December 16, 2024 Letter;
- Plaintiffs' July 8, 2025 Letter;
- Defendants' July 21, 2025 Letter and Exhibits A-G;
- Plaintiffs' July 25, 2025 Post-Hearing Letter and hearing slide deck;
- Defendants' July 28, 2025 Post-Hearing Letter and Exhibits A and B;
- Plaintiffs' August 7, 2025 Letter;
- Plaintiffs' August 9, 2025 Draft Expert Report of Kevin O'Brien and CV;
- Defendants' August 11, 2025 Letter in response to Draft Report of Kevin O'Brien; and
- Emails from the Parties on the issue throughout the discovery process.

I have also held multiple conferences with the Parties, including on January 7, 2025, July 24, 2025, and August 9, 2024.

II. LEGAL STANDARD

Evidence is relevant if (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action. Fed. R. Evid. 401.

Federal Rule of Civil Procedure 26(b)(1) states that parties "may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case considering [(1)] the importance of the issues at stake in the action, [(2)] the amount in controversy, [(3)] the parties' relative access to relevant information, [(4)] the parties' resources, [(5)] the importance of the discovery in resolving the issues, and [(6)] whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). In addition, a court must limit discovery if the information "sought is unreasonably cumulative or duplicative or can be obtained from some other source that is more convenient, less burdensome, or less expensive." Fed. R. Civ. P. 26(b)(2)(C)(i).

The party seeking discovery bears the burden of showing the relevance of the requested information. *See Morrison v. Phila. Housing Auth.*, 203 F.R.D. 195, 196 (E.D. Pa. 2001) ("A party moving to compel bears the initial burden of showing the relevance of the requested information."); *Brewer v. Berks Cty. Sheriff*, No. 5:13-CV-5763, 2015 WL 13620425, at *2 (E.D. Pa. Oct. 5, 2015) ("The party seeking discovery has the burden of showing that the information sought is relevant to the subject matter of the action and may lead to admissible evidence." (citation omitted)). If the requesting party satisfies its burden, "[t]he burden then shifts to the party resisting discovery to justify withholding it." *Morrison*, 203 F.R.D. at 196.

III. DISCUSSION

a. The Parties' Positions

i. Plaintiffs' Position

Plaintiffs argue that the Slides are relevant in that they will allow them to verify the Defendants' representations in studies about the impact of GLP-1 RA's on animals and because they relate to the injuries at issue in this litigation. *See* Pls.' Dec. 11, 2024 Ltr., pp. 1-2. In support of the claimed relevance of the Slides, Plaintiffs point to several requests from the FDA for information about slides in general, such as where they are located or how they relate to issues of gastric emptying. *See* Pls.' Aug. 7, 2025 Ltr.

Plaintiffs also submitted the August 8, 2025 draft expert report of Dr. Kevin M. O'Brien (the "O'Brien Report"). The O'Brien Report explains that the Slides are relevant because they will show the underlying detailed information that went into Defendants' study reports. *See generally* O'Brien Rep. Dr. O'Brien observes that the reports, without the Slides, "do not provide any detailed information about the microscopic findings appearing during histopathological review." *Id.* at 2. According to Dr. O'Brien, "[T]he underlying pathology data is necessary to review and consider the animal studies conducted by the companies with the same evidence available to the companies." *Id.* at 4.

ii. Defendants' Position

Defendants assert that Plaintiffs have failed to carry their burden to demonstrate the specific relevance of the Slides (as compared to the information already in the reports) and are essentially relying on their hypothetical relevance to seek a broad and burdensome production. *See generally* Defs.' July 28, 2025 Ltr.

Defendants assert that the O'Brien Report does not connect the requested pathology to the Plaintiffs' claims. *See* Defs.' Aug. 11, 2025 Ltr., p.1. They observe correctly that Dr. O'Brien does

not reference any specific study (let alone the 22 studies that Plaintiffs have identified). *See* Defs.' Aug. 11, 2025 Ltr. Nor does Dr. O'Brien claim to have read the reports for each of those twenty-two studies or identify which of them he has reviewed. *Id.* Dr. O'Brien notes that "reviewing and peer review pathologists" studied the pathology findings in test animals, but he appears skeptical of their conclusions that the findings are irrelevant to toxicity because he contends they provided "only limited descriptions of the tissues examined." *Id.* at 4. Defendants note that Dr. O'Brien does not identify why the tissue types sought by Plaintiffs are necessary, nor does he suggest any reason to believe they will differ from what is described in the reports. *Id.*

Dr. O'Brien wants to see the actual glass slides to determine "possible etiologies" for the findings described in the study reports, which have been provided to the Plaintiffs, and which Dr. O'Brien has reviewed. *Id.* It appears that Dr. O'Brien bases his need to see the glass slides on the hypothetical possibility that some Slides will contradict some findings in the peer reviewed studies which were based in part on the Slides. It is necessary to balance the possible or hypothetical significance of the Slides against the burden on the Defendants if they are ordered to produce the slides. Defendants argue that Plaintiffs' request "does not come close to justifying the extraordinary time and expense required to access and carefully scan slides for thousands of test animals and multiple tissue types from studies going back as early as 2005 implicated by Plaintiffs' 22 requested studies." *See* Defs.' July 21, 2025 Ltr., p. 1. Defendants note they have already produced millions of pages of documents and that "the safety profile of the products at-issue here has been well established through extensive animal and clinical studies conducted over more than 20 years and more than a decade of real-world patient use." *Id.*

Against this backdrop of extensive animal and clinical studies and in light of the length of time these medications have been used by patients, the burden on the Defendants to produce these

slides outweighs the theoretical, possible significance of the Slides in the Plaintiffs' inquiry into the validity of the peer reviewed findings based on the animal studies.

The Defendants' argument that Plaintiffs have delayed in pursuing the Slides has merit. Plaintiffs first raised the issue of producing these histopathology slides in September 2024, and brought it to me in December 2024, although they did not ask for a resolution during our January 2025 conference. *See* Pls.' Dec. 11, 2024 Ltr. Plaintiffs did not revisit the issue with me until July 2025. *See* Pls. July 8, 2025 Ltr. The Defendants contend "Plaintiffs' six-month delay in providing a threshold explanation of relevance has made it likely impossible to collect and produce all the materials Plaintiffs have requested by the close of fact discovery on October 24, 2025." *See* Defs.' July 21, 2025 Ltr., p. 1.

b. The Rule 26 Analysis

i. The Slides are relevant, but marginally so.

I conclude that the Slides are relevant under Rule 401's very broad definition of relevance. *Gibson v. Mayor and Council of City of Wilmington*, 355 F.3d 215, 232 (3d Cir. 2004). It cannot be said that the Slides have no tendency to prove or disprove issues related to the Defendants' representations to the FDA. *See generally* Fed. R. Evid. 401. Indeed, understanding what the Defendants knew from the Slides and how they then described that information to the FDA could conceivably relate to several issues in the litigation, including preemption defenses and causation. In Case Management Order No. 18, the Court explained that it will need to know "what was provided to the FDA, and more importantly what was withheld from the FDA." *See* Feb. 27, 2025 CMO, p. 18, ¶ 12 [ECF No. 235].

That relevance, however, is marginal. While the Slides could show information was withheld from the FDA, Plaintiffs offer no reason to suggest that occurred. Plaintiffs have not

identified any specific instance in which the content of any animal slides was misrepresented to the FDA. Nor have they described with any clarity why these 22 studies are necessary or significant to understand the information the Defendants provided to the FDA. Essentially, the crux of Plaintiffs' request is that it is theoretically possible that there is some mismatch between what the Defendants' reports say and what the Slides show. While the existence of such a mismatch might conceivably impact issues at stake in this litigation, it is conjectural.

In this regard, I am guided by the discussion of histopathology slides in the *Gardasil Products Liability Litigation* submitted by Defendants. *See* Defs.' July 21, 2025 Ltr., Ex. H. Judge Kenneth D. Bell of the Western District of North Carolina considered a very similar motion for production of animal slides with a very similar nonspecific justification. The Court declined to order the production of these similar tissue samples, suggesting the studies themselves were adequate and that seeking the production of additional slides was a "snipe hunt." *See id.* at 55:15-17. Plaintiffs cite to no instance or case in which histopathological slides of this nature and involving this level of burden were ordered to be produced by a court.

The O'Brien Report does not change the result, nor do the other documents submitted alongside Plaintiffs' August 7, 2025 letter. While Dr. O'Brien provides some basis for the theoretical usefulness of the Slides, he does not provide sufficient detail as to why the Slides from these 22 studies will impact the analysis. Indeed, as Defendants point out, it is not clear he has read the 22 studies. In any event, his opinion simply establishes that Slides could hypothetically be relevant. Likewise, the FDA's inquiries about the locations of the slides or their relation to gastric emptying does not establish that there was some mismatch between the information in the studies (which have been produced) and the Slides.

Accordingly, while I determine that the Slides are technically relevant, I find that on the briefing before me, their relevance is marginal.

ii. The Rule 26(b)(1) factors.

Having determined the Slides have some small amount of relevance, I must consider whether their production is proportionate to the needs of the case. Considering the Rule 26(b)(1) factors, I find their production would be disproportionate and therefore do not recommend their production.[1]

There is no doubt that the first three factors favor production. *See* Fed. R. Civ. P. 26(b)(1). The issues at stake are important; the amount in controversy is high; and Plaintiffs do not have other access to the information contained within the Slides absent their production. But those factors would likely be true for almost any discovery sought by Plaintiffs.

I find the fourth factor (the Parties' resources) to be split, as both sides of this lawsuit have considerable resources. The remaining two factors dramatically outweigh the others.

First, the importance of the Slides to this litigation has not been demonstrated. Plaintiffs' desire to double-check the Defendants' reports could render almost anything in Defendants' possession related to GLP-1 RAs conceptually relevant because it might show that Defendants knew something that they did not report to the FDA. What the Slides will add to the double-checking process other than one more opportunity to capture a potential inconsistency is unknown—this is the "snipe hunt" referred to in *Gardasil*. I have nothing before me, including the

[1] Neither of the parties have extensively discussed these factors in their briefing, but nevertheless I have the facts before me that inform that analysis.

expert report of Dr. O'Brien, that sets forth why the Slides had any particular importance to the FDA's analysis or that suggests they are likely to contain an inconsistency.

The Plaintiffs' delay in seeking the Slides until the end of the discovery period also suggests they are not particularly important to the litigation. Plaintiffs first raised the production of the Slides with me in December 2024, and while the parties engaged in some small back and forth between January and July on these issues, Plaintiffs did not raise the issue of their production again until nearly six months later. This indicates that the Slides are less important to the litigation.

Second, the burden associated with their production is great. Production of the Slides is not simply a matter of handing over digitally collected evidence. The Slides must be imaged through a particular protocol and captured with particularized resolution. *See* Defs.' July 28, 2025 Ltr. p. 1. Defendants note that "Plaintiffs' request involves thousands of test animals and potentially up to 10,000 total pathology slides from studies going back to as early as 2005." *See* Def.'s July 21, 2025, p. 3.

The burden is only magnified by the stage of discovery. Defendants assert that it would likely be impossible to complete this production by the discovery deadline of October 24, 2025. *See* Defs.' July 21, 2025 Ltr., p. 1. Plaintiffs do not provide any explanation of how this collection can be accomplished within the remaining timeframe for discovery. The close of discovery is imminent for this phase. As the Court noted, the discovery schedule will only be extended in this

case upon a showing of "extremely good cause." *See* Mar. 21, 2025 Hrg. Tr. at 9. Absent an amended discovery schedule, accomplishing the production of these slides is unduly burdensome.

Considering the Rule 26(b)(1) factors, I find that production of the Slides would "not be proportional to the needs of the case" and therefore do not recommend their production.

IV. CONCLUSION

For the reasons outlined above, I recommend that the Court enter the proposed Order, attached hereto as Exhibit A, denying Plaintiffs request for production of the Slides.

This Report and Recommendation is filed pursuant to Federal Rule of Civil Procedure 53(e) and Paragraph 14 of Judge Marston's July 31, 2024 Order appointing this Special Master. *See* Order, ¶ 14 [ECF No. 213]. The Parties may serve and file specific written objections to this Report and Recommendation within five (5) business days from this date. Fed. R. Civ. P. 53(f); Order, ¶ 15 [ECF No. 213].

Respectfully submitted,

Date: September 8, 2025

/s/ Lawrence F. Stengel
Hon. Lawrence F. Stengel (Ret.)
Court Appointed Special Master
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